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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,991	01/23/2001	Gary K. Michelson	101.0101-00000	4198
22882	7590	07/02/2004	EXAMINER	
MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			PHILOGENE, PEDRO	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/768,991	<b>Applicant(s)</b> MICHELSON, GARY K.	
	<b>Examiner</b> Pedro Philogene	<b>Art Unit</b> 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-31, 33-54, 56-150 and 152-204 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-31, 33-54, 56-150 and 152-204 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14,18-29,81-91,94-99,199-203,30,31,33,34,62-71,100-109,112-150,195-198,204 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson (6,342,074) in view of Benzel et al. (6,214,005).

With respect to claims 1, 26, 81 Simpson discloses a spinal implant (100) for insertion at least in part across at least the height of a disc space between adjacent vertebral bodies (10,12), the implant comprising opposed upper and lower surfaces (122,124) adapted to be placed toward and in contact each of the adjacent vertebral bodies (22,24), respectively from within the disc space; as best seen in figs. 1,2; a leading end for insertion into the disc space and between the adjacent vertebral bodies; a trailing end opposite the leading end, the trailing end having an exterior surface and an outer perimeter with an upper edge and a lower edge adapted to be oriented toward the adjacent vertebral bodies, respectively, as best seen in Figs. 1-4, the trailing end having a maximum height, as measured from the upper edge to the lower edge along the longitudinal axis of the human spine, the maximum height being adapted to fit within the disc space and between the vertebral bodies adjacent to the disc space; as best seen in Fig: 1; a bone screw (52,54) having a leading end for placement in the vertebral body and a trailing end opposite the leading end adapted to cooperatively engage the

implant so as to prevent further advancement of the bone screw into the bone; a plurality of bone screw receiving holes (152,154) in the trailing end.

With respect to claims 2-14,18-25,26-29,81-91,199-203, Simpson discloses all the limitations, as set forth in column 7, lines 45-67, column 8, lines 1-48, and as best seen in FIGS. 1-3.

It is noted that Simpson did not teach of at least one of the bone screw receiving holes passing through the exterior surface and one of the edges so as to permit the trailing end of the bone screw to protrude beyond the one of the edges; as claimed by applicant. However, in a similar art, Benzel et al evidence the use of a plurality of bone screw holes adapted to only partially circumferentially surround a trailing end of a bone screw adapted to be received therein and passing through an edge to provide better visibility.

Therefore, given the teaching of Benzel et al. it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Simpson, as taught by Benzel et al. to provide better visibility.

Claims 15,16,35-54,56-61,72-80,92-93,110,111,152-194 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson (6,342,074) in view of Benzel et al. (6,214,005) in view of Liu (6,629,998).

With respect to the above claims it is noted that the above combination of references did not teach of a trailing end of a bone screw extending beyond the maximum height of the trailing end of the implant; and one lock for retaining the screw within the implant; as claimed by applicant. However, in a similar art, Liu evidences the

use of a bone extending beyond the maximum height of the trailing end of the implant and a lock to allow a greater micro-motion between the vertebrae and the bone nail thereby promoting the bone growth and retaining means to prevent the screw from coming out.

Therefore, it would have been obvious to one having ordinary skill in the art, at the time the invention was made to modify the device of Simpson/Benzel, as taught by Liu to allow a greater micro-motion between the vertebrae and the bone nail thereby promoting bone growth and retaining means to prevent the screw from coming out.

With respect to claims 152-194, the use of these instruments are old and well known in the medical art, and their uses are not believed to be critical in the operation of the device, as set forth above (see previous rejection).

### ***Response to Amendment***

Applicant's arguments with respect to claims 1-198 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***


A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene  
June 24, 2004



PEDRO PHILOGENE  
PRIMARY EXAMINER